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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,615	12/26/2001	Paul Meers		9551

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/914,615

Applicant(s)
Meers

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

- 2. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim (5,723,147).**

Kim discloses a process of preparation of liposomes in which the lipid in an organic solvent is added with an aqueous solution of an active agent which in turn is added with a second aqueous solution containing lysine. The organic solvent is then removed. Kim teaches various active agents including DNA and RNA (abstract, col. 6, line 62 and Examples). Instant claims do not recite specific complexing agents and the nature of complexing, i.e., whether it is ionic or covalent. Since anions and cations are known to interact to form complexes and since Kim teaches both anionic and cationic active agents (morphine, morphine sulfate and nucleic acids), they would naturally be complexing with lysine (free base) or lysine hydrochloride. The reference thus, meets the requirements of instant claims.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Kim (Cancer Research 53, pp. 1596-1598, April 1993).

Kim discloses a process of preparation of liposomes in which the lipid in an organic solvent is added with an aqueous solution of an active agent which in turn is added with a second aqueous solution containing lysine. The organic solvent is then removed (Materials and Methods section on col. 2, page 1596).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (5,723,147) cited above.

The teachings of Kim have been discussed above. Kim does not teach the addition of the complexing agent to the lipid solution first followed by the addition of the active agent solution. Since complexing occurs between the active agent and the complexing agent irrespective of which one is added first, instant method steps are deemed to be manipulatable steps practiced by an artisan.

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6. **Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (5,759,573).**

Instant method claims are drawn to formation of liposomes wherein the active agent is complexed with a complexing agent; the method steps in claims 1 and 2 recite two variables. 1) the complexing agent is added in the second aqueous solution whereas the active agent is added in the first aqueous phase (claim 1); 2) the complexing agent is added in the first aqueous medium and the active agent is added in the second aqueous medium.

Kim discloses a process of preparation of liposomes in which the lipid in an organic solvent is added with an aqueous solution of an active agent which in turn is added with a second aqueous solution. The organic solvent is then removed. In Kim's process, the complexing agent, cyclodextrin is added in the first aqueous phase together with the active agent (col. 4, lines 13-26 and Example 1).

However, it would have been obvious to one of ordinary skill in the art to manipulate the basic process of preparation of liposomes, i.e., adding the complexing agent and the active agent together in the same aqueous medium with the expectation of obtaining liposomes with similar complexes because one of ordinary skill in the art would reasonably expect the complexation between the active agent and the complexing agent to occur, irrespective of whether they are added together in the same phase or separately in two phases. Kim does not specifically teach the active agent to be a nucleic acid. However, in view of Kim's teachings that the method is applicable to any active agent, it is deemed obvious to one of

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ordinary skill in the art to use DNA or RNA as the active agent with a reasonable expectation of success.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

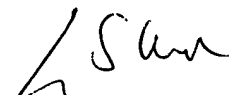
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility

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that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 28, 2003